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EXAMINER	
CHEU, CHANGHWA J	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,494	MATSUURA, EIJI	
	Examiner	Art Unit	
	Jacob Cheu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *6-11,18-20 and 25* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 12-17, 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, 12-17, 21-24, drawn to a standard comprising complex having oxidized LDL bound covalently to beta2-GPT.

Group II, claim(s) 6-9, drawn to a method of measuring the *complex* of oxidized LDL bound covalently to beta2-GPT.

Group III, claim(s) 10-11, drawn to a method of detecting a disease comprising measuring the complex of oxidized LDL bound covalently to beta2-GPT.

Group IV, claim(s) 18-20, drawn to a method of measuring *antibody* recognizing complex oxidized LDL bound covalently to beta2-GPT.

Group V, claim(s) 25, drawn to a method of measuring an immune complex comprising an anti-IgG antibody.

The application contains claims to more than one of the combinations of categories of inventions as set forth by 37 CFR 1.475.

According to 37 CFR 1.475 regarding unity of invention:

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) above, unity of invention might not be present. Furthermore, the determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

Accordingly applicant is entitled to have product (Group I), or any method (Group II-V), or product with *ONE* method of using, e.g. Group I/II, I/III, I/IV or I/V, be examined (See 37 CFR 1.475 (b)2).

2. A telephone call was made to Mr. Cheek on 11/1/2007 to request an oral election to the above restriction requirement, and applicant responded in facsimile on 11/7/2007 by electing Group I, claims 1-5, 12-17, 21-24 without traverse. It is noted that applicant's election of Group I contains claims 7-9 which depends on Group II independent claim 6. Since applicant had elected Group I, claims 6-9 would be withdrawn from further consideration.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

3. Currently, claims 1-5, 12-17, 21-24 are under examination. Claims 6-11, 18-20 and 25 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13, 15-17, 21-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 13, it is noted that applicant recites "which further comprises "antibody recognizing 'oxidized LDL/β2-GPI complex'''. Such language is confusing and indefinite. Particularly applicant uses different quotation marks, i.e. ", ', '". It is suggested that applicant simply recites "comprising antibody capable of recognizing the oxidized LDL/β2-GPI complex as a constituent ingredient.

Similarly, claims 15-16, 22-23, suffer from the same problem as appears in claim 13. Correction is needed.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 15-17, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuura et al. (US 5900359; applicant submitted IDS on 6/10/2005).

Matsuura et al. teach an immunological complex associated with lipoproteins. Matsuura et al. teach that such complex can be formed by addition of oxidized LDL with a β2-GPI

solution, and the resulting product is the complex of oxidized LDL/β2-GPI complex (Col. 8, line 55-65).

With respect to the intended use as a "standard for measuring of this complex", applicant is reminded that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963). Furthermore, although Matsuura et al. do not explicitly disclose the structure of the complex, i.e. covalent bound of the oxidized LDL with the β2-GPI, one ordinary skill in the art would recognize such a feature as an inherent characteristic because the interaction of the molecules.

With respect to claims 2 and 16, applicant recites the complex would be *"obtainable"* by incubating under 37C and pH 7.4 for 16 hours (emphasis added). The case law has established that the production of a product by a particular process does not impart novelty or unobviousnes to a product when the same product is taught by the prior art- "[Where] the claimed and prior art products are identical or substantially identical in *structure or composition*, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)(emphasis added). This is particularly true when the properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPQ 964 (CAFC 1985); In re Marosi, 218 USPQ 289, 292-293 (CAFC 1983); In re Brown, 173 USPQ 685 (CCPA 1972). Therefore, even if a particular process used to prepare a product is novel and unobvious over the prior art, the product per se, even when limited to the particular process, is unpatentable over the same product taught by the prior art. See In re Kind, 207 F.2d 618,

620, 43 USPQ 400, 402 (CCPA 1939); In re Merz, 97 F.2d 599, 601, 38 USPQ 143, 144-145 (CCPA 1938); In re Bergy, 563 F.2d 1031, 1035, 195 USPQ 344, 348 (CCPA 1977) *vacated* 438 U.S. 902 (1978); and United States v. Ciba-Geigy Corp., 508 F. Supp. 1157, 1171, 211 USPQ 529, 543 (DNJ 1979).

With respect to claims 3 and 17, as discussed above, the product would inherently posses the similar properties as recited in the claim language.

With respect to claims 4-5, Masuura et al. teach that the complex can be used to detect blood samples from the patients of diabetic arteriosclerosis, myocardial infarction or cerebral infarction (Col. 12, line 15-30).

With respect to claim 15, the complex can be recognized by antibody (Cof-22)(Col. 8, line 62-68).

8. Claims 1-5, 15-17, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kobayashi et al. (J Lipid Research 2001 Vol. 42, page 697-709; applicant submitted IDS information on 6/10/2005).

Kobayashi et al. teach an immunological complex associated with lipoproteins. Kobayashi et al. teach that such complex can be formed by addition of oxidized LDL with a β2-GPI solution, and the resulting product is the complex of oxidized LDL/β2-GPI complex (See Figure 2-3 and 12; particularly Figure 12 oxLig-1 is an oxidized LDL).

With respect to the intended use as a "standard for measuring of this complex", as discussed above, if the prior art structure is capable of performing the intended use, then it meets the claim. Similarly, one ordinary skill in the art would recognize the feature of "covalent bound" between the oxidized LDL and β2-GPI as an inherent characteristic because the interaction of the molecules.

With respect to claims 2 and 16, applicant recites the complex would be *"obtainable"* by incubating under 37C and pH 7.4 for 16 hours (emphasis added). As the case law discussed above, "[Where] the claimed and prior art products are identical or substantially identical in *structure or composition*, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established." In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977)(emphasis added).

With respect to claims 3 and 17, as discussed above, the product would inherently posses the similar properties as recited in the claim language.

With respect to claims 4-5, Kobayashi et al. teach that the complex can be used to detect blood samples from the patients, such as antiphospholipid syndrome (APS)(See Abstract).

With respect to claim 15, the complex can be recognized by antibody (EY2C29, WB-CAL-1)(See page 698, right column, third paragraph).

With respect to claim 21, Kobayashi et al. teach using a solid support for immobilizing the complex for detection (See Figure 12).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole

would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 12-13, 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuura et al. or Kobayashi et al. in view of Zuk et al.(US 4208479).

Both Matsurra and Kobayashi et al. reference have bee discussed above but do not explicitly teach a kit for use of the complex.

Zuk et al. teach that in performing assays, it is convenient and to combine the necessary reagents together in a kit (col. 22, lines 20-35). Zuk et al. further teach that this may improve assay accuracy.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have motivated Matsurra or Kobayashi et al. to place the oxidized LDL/β2-GPI complex into a kit as taught by Zuk et al. for convenience, standardization, and improved accuracy of the assay.

With respect to claims 13 and 22-23, Matsurra et al. teach an antibody (Cof-22) recognizing the complex of the oxidized LDL/β2-GPI complex (Col. 8, line 55-70). The antibody is labeled with peroxidase. Supra.

With respect to claims 14 and 24, Matsurra et al. teach that the the complex can be used to detect blood samples from the patients of diabetic arteriosclerosis, myocardial infarction or cerebral infarction (Col. 12, line 15-30).

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641

12/10/07

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